K081036

MAY - 9 2008

Premarket Notification 510(k) Summary

Submitter's Name:

Varian Medical Systems, Inc.
3100 Hansen Way E-110
Palo Alto, CA 94304
Contact Name: Vy Tran
Phone: (650) 424-5731
Fax: (650) 424-5040
Date: April 9, 2008

Proprietary Name: 4D Integrated Treatment Console

Classification Name: Medical charged-particle radiation therapy system, 21 CFR 892.5050, IYE, Class II

Common/Usual Name: 4DITC

Predicate Devices: 4D Integrated Treatment Console, K050479

Device Description: The 4D Integrated Treatment Console (4DITC) has been modified to add a new capability called Patient Accessory Verification System (PAVS). PAVS is a feature set of 4D ITC that enhances treatment safety. This feature allows users to identify accessories (not connected to the linac) for patients and interlock the radiation beam until these devices have been acknowledged by the end-user. Also, PAVS allows patient verification between the patient on the treatment schedule with the patient in the treatment room. This is accomplished using a hand-held bar code scanner used in conjunction with software by trained clinical staff. Staff defines which accessories require a bar code label to be scanned. Clinical staff creates the labels for the accessories using label creation software in Practice Management and a label printer. Staff scans the appropriate accessories for each patient's treatment field for accessory selection verification.

Statement of Indications for Use: The 4DITC function is designed to assist the operator of a radiation therapy device in providing accurate treatment setups for each patient by monitoring setup parameters and preventing the radiation therapy device from commencing irradiation when any parameter is out of conformance with the treatment plan.

Technological Characteristics: Refer to the Substantial Equivalence Comparison Chart.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 9 2008

Ms. Vy Tran
Corporate Director, Regulatory Affairs
Varian Medical Systems, Inc.
3100 Hansen Way
PALO ALTO CA 94304

Re: K081036
Trade/Device Name: 4D Integrated Treatment Console
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: April 8, 2008
Received: April 11, 2008

Dear Ms. Tran:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4D Integrated Treatment Console

Indications for Use

510(k) Number (if known): K081036

Device Name: 4D Integrated Treatment Console

Indications for Use:

The 4DITC function is designed to assist the operator of a radiation therapy device in providing accurate treatment setups for each patient by monitoring setup parameters and preventing the radiation therapy device from commencing irradiation when any parameter is out of conformance with the treatment plan.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K081036